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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,492	12/30/2003	E. C. Henley	050152/NHN.0085.US00	8733

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/748,492	Applicant(s) HENLEY, E. C.	
	Examiner Ganapathy Krishnan	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8-13 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 8-13 and 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A Request for Continued Examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed 12/14/2006 has been entered.

The following information provided in the Request for Continued Examination affects the instant application:

1. Claims 2, 7 and 14-15 have been canceled.
2. New Claim 21 has been added.
3. Claims 1 and 18 have been amended.
4. Remarks drawn to rejections under 35 USC 112, 102, 103 and double patenting.

Claims 1, 3-6, 8-13 and 16-21 are pending in the case.

Claim Rejections - 35 USC § 112

The rejection of claims 15 and 18 under 35 USC 112, second paragraph advanced in the final rejection has been overcome since applicants have pointed out to the specification wherein a clear definition is provided for the terms "soy protein material". Therefore the rejection is withdrawn.

Double Patenting

The rejection of claims 1-15 under obviousness-type double patenting has been overcome by amendment, which mutually excludes the instant claims. The amendment is also supported by the specification (page 18, examples 1-2). The rejection is withdrawn.

Claim Rejections - 35 USC § 102

The rejection of claims 1-14 and 16-17 under 35 U.S.C. 102(b) as being anticipated by Kelly et al (WO 98/08503) advanced in the final rejection has been overcome by amendments to claim 1, for which support is seen in the specification (page 18, examples 1-2). The rejection is withdrawn.

Claim Rejections - 35 USC § 103

The rejection of claims 18-20 under 35 U.S.C. 103(a) as being unpatentable over Kelly et al (WO 98/08503) in combination with Potter et al (US 6,326,366) advanced in the final rejection has been dropped in view of the amendments to claim 18. The rejection of claim 15 has been rendered moot by cancellation of the claim.

The following art rejection is made of record.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 3-6, 8-13 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al (WO 98/08503, '503; document cited in IDS of May 25, 2006) in combination with Kelley (WO 93/23069, '069).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Kelly et. al ('503) teach a method prophylaxis and treatment of urinary incontinence using a composition comprising genistein (page 6, lines 6-11). In formula (I) (page 1) of Kelly when Z is H, R1 is H, R2 is OH, W is H and A and B taken together is the structure at the bottom left at page 1 and Y is OR7 and R7 is H, reduces to genistein. The amount of the active agent used in the composition in general is 0.1 to 2g (page 9, lines 12-16). Kelly et al teach compositions of the compounds of their invention suitable for oral, rectal, optical buccal, parenteral and transdermal administration. The formulations include capsules tablets suspension, solutions excipients (page 9, line 18 through page 12, line 5). The active agents may be provided with foodstuff, health bars and desserts (page 12, lines 7-11). The composition used in the method is for administration to humans. However, Kelly ('503) teaches several isoflavones that could be used in the said composition and does not specifically point out to genistein.

Kelley ('069), drawn to phytoestrogens, teaches that isoflavones like genistein, daidzein, formononetin, biochanin A and their natural glycosides or their analogs have health improving

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effects and are useful for ameliorating health conditions like cancer and high cholesterol levels (page 8, third full paragraph). Kelly ('069) also teaches that small proportions of these isoflavones is absorbed from the bowel and circulate in the blood (page 9, middle paragraph). This teaching of Kelly suggests that a higher intake of the isoflavones is needed in order to increase the concentration of the isoflavones in the blood. The preferred administration amounts for humans as taught by Kelly is 20-200mg on a daily basis and the more preferable being from 50-150mg. The desired dosages can be increased for therapeutic reasons and dosages greater than 1000mg may be suitable for treating some conditions (page 14, middle paragraph). The isoflavones of Kelly are present in common foodstuff like soya (page 1, last paragraph through page 2, line 2). This teaching suggests that consumption of soya materials would increase the uptake of the isoflavones.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a composition comprising isoflavones in combination with soy protein material in a method of treatment as instantly claimed since such a method using the active agents is seen to be taught in the prior art.

One of ordinary skill in the art would be motivated to use a composition comprising the isoflavones as instantly claimed in a method as instantly claimed since soy protein material is also the source of the said isoflavones and their glycosides and using a composition comprising soy protein materials will have an additive effect in the said treatment. One of ordinary skill in the art would also be motivated to the use of the isoflavones as instantly claimed since genistein as taught by Kelly above has anticancer and cholesterol reducing properties in addition to treating urinary incontinence. One of ordinary skill in the art would also substitute other analogs

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that are structurally close to genistein in order to look for compounds that have a higher therapeutic value.

It is well within the purview of one of ordinary skill in the art to adjust dosages of the active agents in order to optimize the beneficial effects.

Conclusion

Claims 1, 3-6, 8-13 and 16-21 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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GK

A handwritten signature in black ink, appearing to read 'SJD 1/18/07', is written over a horizontal line.

Shaojia Jiang
Supervisory Patent Examiner
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